



Testimony of Margaret A. Hamburg, M.D.
Vice President of Biological Programs, Nuclear Threat Initiative
Senate Committee on Governmental Affairs
June 28, 2002

Mr. Chairman and members of the Committee, thank you for the invitation to participate in this hearing. My name is Margaret (Peggy) Hamburg. I am a physician and a public health professional, currently serving as Vice President for Biological Programs at NTI, a private foundation, co-chaired by Ted Turner and Sam Nunn, whose mission is to reduce the global threat from weapons of mass destruction. I have previously served in government at various levels including Assistant Secretary for Planning and Evaluation in the Department of Health and Human Services in the last Administration, six years as New York City Health Commissioner (under both Mayor Dinkins and Mayor Giuliani), and Assistant Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health. I am pleased to have the opportunity to discuss issues surrounding the creation of a new Department of Homeland Security and the policy implications for public health and bioterrorism threats. Your interest in and commitment to these concerns are greatly valued.

Events this past fall - including the attacks of September 11 and the dissemination of anthrax through the postal system - demonstrated our nation's vulnerability to terrorism, and dramatically underscored both the need and complexity of homeland defense. There is an urgent requirement to strengthen planning, coordination, implementation and oversight of efforts to improve homeland security.

I strongly applaud current efforts to give greater authority and accountability to our homeland security program, including the creation of a new federal Department of Homeland Security. There is a strong rationale for consolidating some of the many departments and agencies that share similar functions or provide various aspects of what is needed for comprehensive preparedness and response. Both the Administration's Bill to establish a Department of Homeland Security and S. 2452 to establish a Department of Homeland Security and a National Office for Combating Terrorism as introduced by Senator Lieberman and colleagues, offer important opportunities to strengthen leadership, focus and coordination of essential programs and policies. However, they also raise a number of critical concerns that must be surfaced, discussed and addressed.

It is increasingly evident that effectively preparing our nation against the threat of terrorist attack requires well-defined authority, accountability and coordination / integration across an exceedingly broad array of agencies and activities. The existing Office of Homeland Security, despite the yeoman efforts of Governor Ridge and his staff, is clearly not structured to achieve this task. The formation of a new Department of Homeland Security, at a cabinet level, can potentially make a very real and enduring difference to efforts to plan, coordinate and integrate U.S. government activities relating to homeland security particularly in such realms of overlapping/shared activity as border security, customs procedures and aspects of emergency response, in order to achieve greater efficiency, effectiveness and accountability. How best to

address the activities related to bioterrorism prevention, preparedness and response is a more complicated question.

In my testimony this morning, I want to briefly raise a number of issues that apply broadly to the creation of a new Department of Homeland Security, but then focus most of my attention on the issues that specifically relate to the biological threat.

DEPARTMENT OF HOMELAND SECURITY: SOME BROAD CONCERNS

With respect to a new Department of Homeland Security, we need to move forward, but do so carefully, with great thought and consideration as to what are the goals and how best can we achieve them. Several important concerns come to mind:

Need for a Strategic Framework

The creation of a new Department of Homeland Security represents an ambitious undertaking which will be enormously difficult to implement and very disruptive to many functions and activities for a considerable period of time. Realistically, even under the best of circumstances, we will lose time and forward momentum in our current programs as we undertake this effort. Thus the goals of the reorganization must be well defined before legislation enacting this Department is passed. We should be very clear about what we are doing and why. This is not the time to undertake change unless we are certain it will provide needed longer-term gains. A truly meaningful reorganization should be done in the context of an overall strategic plan or framework for action that defines goals and objectives, as well as the related roles and responsibilities of the various component partners.

Need for Balance

Current approaches require that a great many agencies and agency components be pulled into one large Department focused primarily on terrorism preparedness and response. However, this new Department of Homeland Security will still be responsible for dealing with a broad range of other activities. Many of these more routine activities will be important to the core Departmental mission because they will, on a regular basis, allow for the practice of systems that would be recruited into service in the event of an attack (e.g. disaster response and sheltering, FEMA). Similarly, routine non-terrorism activities might serve to identify unusual patterns or situations that might signal an impending terrorist event (e.g. monitoring shoreline for drug-runners or boating accident rescues, Coast Guard). However, there is serious concern that when you create a Department as diverse as this one would be, you will either lose focus on the organizing mission of countering terrorism or you will fail to effectively support those other routine functions. It is hard to imagine a Department remaining honed in on terrorism preparedness and response while responding to mudslides, hurricanes and fires, monitoring the fisheries, searching out drug traffickers, controlling hog cholera and investigating outbreaks of disease. It is also hard to imagine effective leadership for such a diverse array of tasks, requiring an equally diverse array of professional backgrounds and expertise.

Need to Address Existing Weaknesses (Not Just Move Pieces Around)

Given the above concerns about managing this complex and varied new Department, serious questions must be raised as to how known weaknesses in certain of the component agencies and activities will be systematically and effectively addressed. Merely rearranging the organizational structure will not resolve many of these deeply entrenched problems. Some of the problems may benefit from new leadership or enhanced attention and scrutiny, however, without a clear game plan and focused strategy, others may continue to fester, or worse, their continuing dysfunction may be amplified in a new and confusing bureaucracy. A host of personnel, budgetary and jurisdictional issues may add to the difficulties of providing appropriate oversight, management and operational accountability.

Need to Maintain Program Connectivity / Coherence

In several domains, but particularly with respect to bioterrorism, the creation of a new and distinct Department may serve to disconnect certain functions such as bioterrorism surveillance, laboratory networks and response from the infrastructure needed to respond to routine, non-intentional public health issues. The response to a disease outbreak, whether naturally occurring or intentionally caused, will require the same critical components. Most likely, we will not initially know the cause of an emerging epidemic. What is more, our overall infrastructure for infectious disease recognition and response is far from robust. We must be careful not to further fragment our capacity, and inadvertently undermine our own best interests. We must also avoid the unnecessary development of duplicative systems at a time of limited resources.

HOMELAND SECURITY AND THE BIOLOGICAL THREAT

As our nation prepares to respond to the looming concerns posed by bioterrorism, both the nature of the threat and the role of public health, medicine and science continue to be poorly understood and underemphasized. The threat of bioterrorism is fundamentally different from other threats we face, such as "conventional" terrorism or attack with a chemical or nuclear weapon. By its very nature, the bioweapons threat – with its close links to naturally occurring infectious agents and disease – requires a different paradigm.

Furthermore, public health has not been traditionally viewed as an element of national security. Understandably, those working on matters of national security are much less familiar with the public health system – what it is, how it works and why it is important to our overall mission of protecting the nation. For too long, public health has been neglected or overlooked. However, as the threat of bioterrorism illustrates so profoundly, public health is an essential form of public safety and must be a fundamental pillar in our national security framework.

It is not surprising that the various Commission Reports (e.g. Hart–Rudman) that have looked at national security/terrorism issues and current legislative proposals for the creation of a federal Department of Homeland Security have had trouble conceptualizing an appropriate organizational approach that includes bioterrorism preparedness and other biodefense activities. In fact, there is no clear and simple answer to the question of how best to organize the components of an effective bioterrorism prevention, preparedness and response program.

Critical Elements of a National Response

Addressing the question of organization, of course, requires definition of the tasks before us. In this time of heightened anxiety and concern, our nation has a real opportunity – and obligation – to make sure that we have in place the programs and policies necessary to better protect ourselves against this threat, and to attempt to prevent such an attack from occurring at all. While there are many challenges, we do know a great deal about what needs to be done and how to do it. A national response to bioterrorism must incorporate the following elements.

- (1) **Prevention**. Every effort must be made to reduce the likelihood that dangerous pathogens will be acquired or used by those that want to do harm. This must include improving intelligence, limiting inappropriate access to certain biological agents and efforts to establish standards that will help prevent the development and spread of biological agents as weapons.
- (2) **Strengthening public health**. Rapid detection and response will depend on a well-trained cadre of trained public health professionals to enhance disease surveillance and outbreak investigation, educated and alert health care providers, upgraded laboratories to support diagnosis and improved communications across all levels of government, across agencies and across the public and private sector.
- (3) **Enhancing medical care capacity**. We must improve treatment for victims of an attack by enhancing local and federal emergency medical response teams, training health professionals to diagnose and treat these diseases, developing strategies to improve the ability of hospitals to rapidly increase emergency capacity and providing necessary drugs or vaccines where they are needed through the National Pharmaceutical Stockpile.
- (4) **Research**. A comprehensive research agenda will serve as the foundation of future preparedness. Perhaps most urgently, we need improved detectors/diagnostics, along with better vaccines and new medications.

Some of these activities are already underway, but need to be strengthened and extended. Other programs and policies still need to be developed and implemented. Clearly these activities are all essential for homeland security. Yet it is important to note that while certain aspects of these activities are required to respond to the threat of bioterrorism specifically, these programs are just as important for the day-to-day, routine activities of public health and medical care.

Potential Benefits of Inclusion in a New Federal Department

There are certain real advantages that might be gained from placing these programs within a new federal Department of Homeland Security. Perhaps first and foremost, the biological threat, and the necessary programs to address it, is of profound importance to our national security. These activities require greatly enhanced priority and support. By residing within this new Department they may be more likely to command that needed attention and support. Furthermore, experts in biological weapons threats, biodefense and public health preparedness must be full partners at the national security table, participating in strategic planning, policymaking and program design

and implementation. Being part of the Department of Homeland Security might help to institutionalize this important participation.

In addition, very legitimate concerns have been raised that if not housed within this new Department, crucial public health and bioterrorism programs may be neglected, especially over time. Furthermore, important operational public health and biomedical defense functions may not be integrated with national security objectives¹.

Clearly, there is an urgent need for improved coordination and integration of bioterrorism programs and policies across agencies of government. The current patchwork – of programs that address bioterrorism prevention, preparedness and response, including research – is inadequate and unacceptable. These need to be brought together into a collective programmatic vision, and implemented in a manner that sets priorities, supports synergy, identifies gaps and avoids unnecessary overlap or duplication. To date, this has proved a difficult challenge. One might argue that the most effective way to address this concern is to pull these activities together under one roof.

The picture is further complicated by the fact that state and local government entities are also critical elements of bioterrorism preparedness and response. They too must be integrated into an effective vision and framework for action. Similarly the private and voluntary sector, importantly including the medical care system and the pharmaceutical industry, are significant players in a comprehensive approach to combating the threat of bioterrorism. Looking at the federal government from the outside, it can be very confusing to discern where and how best to interact with the system. Again, the creation of a unified site within a Department of Homeland Security might reduce confusion, strengthen the ability to work across levels of government and support the kinds of public–private partnerships that will prove essential to success.

Potential Disadvantages of Inclusion in a New Federal Department / Recommendations

While there may be benefits to be gained by moving certain aspects of bioterrorism and related public health issues into a consolidated new Department of Homeland Security – some profound and some more cosmetic – we must look carefully at the broader question of how best to address these threats so that our overall governmental effort is maximally effective. Certainly there are some notable concerns, at least in the form suggested by the Administration's proposal. I want to outline a few specific examples for examination and discussion , and offer some selected recommendations.

Organization of Bioterrorism Activities

As currently envisioned, the proposed Department of Homeland Security would seek to develop a single, government–wide, comprehensive and integrated research and preparedness plan to prevent chemical, biological, radiological and nuclear (CBRN) attacks, to reduce our nation's vulnerabilities to terrorism and to minimize damage and assure effective response should an attack occur.

¹ O'Toole, Tara. "Creating the Department of Homeland Security: Consideration of the Administration's Proposal." Testimony before the House Subcommittee on Oversight and Investigations, June 25, 2002

This approach is intrinsically troubling, because as noted earlier, the bioterrorism threat has some very distinctive features as compared to "conventional" terrorism or other weapons of mass destruction. Past experience tells us that many so-called bioterrorism programs failed to achieve their potential because they were addressed within the framework of CBRN or "Chem/Bio". There was an underlying assumption that these problems could be effectively approached with a "one size fits all" model, but in reality, such programs simply failed to address the biological component. This may be more of a semantic problem than a conceptual one at this time, but we must guard against falling into that old trap.

Meaningful progress against this threat depends on understanding it in the context of infectious and/or epidemic disease. It requires different investments and different partners. Until the true nature of bioterrorism is fully recognized, our nation's preparedness programs will continue to be inadequately designed: the wrong first responders will be trained and equipped; we will fail to fully build the critical infrastructure we need to detect and respond; the wrong research agendas will be developed; and we will never effectively grapple with the long-term consequence management needs that such an event would entail. We may also miss critical opportunities to prevent an attack from occurring in the first place.

Recommendations:

- (1) The new Department of Homeland Security will require significant expertise in public health, infectious disease and biodefense/bioterrorism. This must be seen as an important priority. Individuals with appropriate background and experience must be represented at the highest levels of leadership and decision-making.
- (2) The appointment of an Undersecretary for Biological Programs should be considered to oversee and integrate the various activities going on within the Department of Homeland Security that relate to the biological threat. In addition, that individual might be charged with liaison responsibility to the various other Departments with significant responsibilities and programs in the biological arena.
- (3) An external advisory group for biological programs might have value to ensure periodic review of the appropriateness and comprehensiveness of issues such as biological threat related programs, policies and resource allocation / budget priorities.

Emergency Response/Role of Public Health Infrastructure

As noted earlier, a bioterrorism attack would differ in fundamental ways from other forms of terrorist assault. The requirements for effective bioterrorism preparedness and response are, for the most part, substantially different as well. Biological terrorism is not a "lights and sirens" kind of attack. Unless the release is announced or a fortuitous discovery occurs early on, there will be no discrete event to signal that an attack has happened, and no site you can cordon off while you take care of the casualties, search for clues and eventually clean up and repair the damage. Instead, a biological terrorism event would most likely unfold as a disease epidemic, spread out in time and place before authorities even recognize that an attack has occurred. We would know we had been attacked only when people began appearing in their doctor's office or emergency rooms with unusual symptoms or inexplicable disease. In fact, it may prove difficult

to ever identify the perpetrators, the site of release, or even determine whether the disease outbreak was intentional or naturally occurring.

Under most circumstances, the "first responders" to a bioterrorism event would be public health officials and health care workers. "Ground zero" will be in hospitals, health care facilities and laboratories. The critical "battlefield" response activities for bioterrorism will unfold through disease diagnosis, outbreak investigation, treatment of the sick and public health actions required to stop continuing contagion and stem disease. How swiftly we recognize and respond to a potential attack will dramatically influence our ability to reduce casualties and control disease. All of these recognition and response functions are more closely tied to public health and medical care activities that respond to naturally occurring infectious disease threats than to the emergency response required for other types of catastrophic terrorism or even other kinds of natural disasters.

In the months since 9/11, the Bush administration – through programs developed and administered by the HHS Office of Public Health Preparedness (OPHP) and the Centers for Disease Control and Prevention (CDC) – has made some progress in building the programs necessary to strengthen public health infrastructure for bioterrorism within this broader context of infectious disease. If these programs are carved out and moved into this new Department, it will disconnect bioterrorism preparedness from other essential components of infectious disease response and control, thin out already limited expertise and enormously complicate the ability of our public health partners at the state and local level to work effectively. If the nation develops two parallel systems for infectious disease surveillance and response – one (that for bioterrorism) of which is only really activated and practiced in a crisis – the likely outcome will be to weaken and fragment our nation's capacity to respond to infectious disease, rather than to strengthen it, whether that infectious disease threat is naturally occurring or intentionally caused.

Recommendations:

- (1) HHS and CDC should continue to have direct responsibility for programs related to the public health infrastructure for infectious disease recognition, investigation and response, including bioterrorism.
- (2) A public health professional with appropriate background and experience could be placed within the Department of Homeland Security with dual reporting to the DHS Secretary and the HHS Secretary. This individual could then work closely with the CDC Director to achieve mutually agreed upon public health priorities for bioterrorism preparedness and response
- (3) The Department of Homeland Security should assure greater coordination, collaboration and program integration among the components of government doing infectious disease surveillance activities (e.g. DOD, USDA, Wildlife and Forestry).

Biodefense Research

Further investments must be made in biomedical research to develop new drugs, vaccines, rapid diagnostic tests and other medical weapons to add to the arsenal against bioterrorism. It is also essential that we improve technologies to rapidly detect biological agents in environmental

samples and develop other technologies to protect the health of the public. We must learn more about how these organisms cause disease and how the human immune system responds so that we can develop better treatments and disease containment strategies to protect us in the future. In addition, we must also invest more focus and resources on "systems research," in an effort to understand more about such issues as personal protective gear, environmental safety and decontamination.

Success will entail research endeavors and collaboration involving multiple agencies of government (HHS, DOD, DOE, USDA and others), academia and the private sector. Coordination of the development and budgetary support for such a comprehensive, integrated biodefense research agenda could certainly be offered under the auspices of the proposed Department of Homeland Security. This can help make sure that crucial links between national security needs and research and development priorities get made, as well as assure proper balance and integration of the bioterrorism related research activities of the various mission agencies, including threats to humans, animals and crops. Hopefully, this would help foster proper recognition and support for elements of the research enterprise which are currently undervalued/under-resourced – such as the United States Army Medical Research Institute for Infectious Diseases (USAMRIID) and the Department of Agriculture's animal health research facility, Plum Island – as well as identify program gaps, overlap and opportunities for synergy.

However, the role of the Department of Homeland Security should be that of coordinator/facilitator. The actual design and implementation of the research agenda and its component programs must remain at the level of the mission agencies, where the scientific and technical expertise resides. With a few possible exceptions, it would be unrealistic and inefficient to build the kind of sophisticated scientific expertise necessary to take on the direct conduct or management of research and development activities across a broad range of disciplines and technologies at the level of this new Department.

Recommendations:

- (1) A research coordination office should be established within the Department of Homeland Security and charged with responsibility for assuring the development and funding support for a comprehensive, integrated biodefense research agenda. An individual with appropriate scientific background and experience would head this office. The possibility that this individual might have dual reporting to the Secretary of HHS or NIH/NIAID Director, as well as to the Secretary of the Department of Homeland Security should be considered, given the fact that HHS is the primary department with responsibility for biomedical research, and the unique role played by NIH.

This research coordination office could also help support the integration of threat and vulnerability analysis with the research priority setting process.

- (2) An external advisory mechanism should be established to encourage ongoing communication and collaboration with academic and industry partners. New mechanisms must be developed to engage participation from outstanding scientists from academe and industry, and to bring new young scientists into these endeavors.

- (3) Our nation faces a crisis with respect to the development and production of new vaccines and antimicrobial drugs. This is not a new concern, but the urgency to meaningfully address it is dramatically increased in light of the bioterrorism threat. High-level commitment and political will is needed. Consideration should be given to the possible role of the Department of Homeland Security, working closely with the appropriate agencies of government (e.g. FDA, NIH, DOD), industry and Congress, to provide leadership and accountability in addressing this concern and defining solutions.

CONCLUDING REMARKS

Few tasks are more important than that of effectively strengthening our nation's security and protecting the health of the public. There are many more outstanding concerns that will need to be clarified and addressed before such important legislation is passed. I deeply respect your efforts, Mr. Chairman, and those of the members of the committee, to take on this vital but difficult challenge. I welcome the opportunity to assist you in this work and would be happy to answer any questions you may have.